REMARKS

Claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-161 are pending in the present application. Claims 2, 5-7, 9-11, 17-18, 20, 22, 25, 27-28, and 30-138 have previously been cancelled without prejudice or disclaimer. Applicants respectfully point out to the Examiner that claim 6 has previously been canceled and is not currently pending in the present application, despite the indication in the present Official Action that this claim remains pending.

Claim 1 has been amended to recite, in part, "wherein the pharmaceutical composition upon actuation with a propellant forms a foam or mousse." Support for this amendment appears throughout the specification and claims as originally filed. No new matter has been added. Applicants, by amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any claim. Applicants reserve the right to reassert any of the claims canceled or the original claim scope of any claim amended herein, in a continuing application.

Submitted herewith is a Declaration under 37 CFR §1.132 by John Richard Buchta, Director of Stiefel Research Australia Pty. Ltd., which is the assignee of the present application. The Declaration evidences the commercial success of the presently claimed pharmaceutical composition and methods of using the same.

In view of the following, further and favorable consideration is respectfully requested.

I. 103 REJECTIONS:

A. At page 5 of the Official Action, claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, 139, 141-144, 146-151, and 153-160 have been rejected under 35 USC § 103 (a), as being unpatentable over Peck et al. in view of Yu et al.

B. At page 15 of the Official Action, claims 140, 145, 152, and 161 have been rejected under 35 USC § 103 (a), as being unpatentable over Peck et al. in view of Yu et al., and further in view of Uchikawa et al.

Regarding rejection **A**, the Examiner asserts that "It would have been obvious to one of ordinary skill in that the art at the time the invention was made to combine the teachings of Peck and Yu et al. and utilize the instant acid" because "Yu teaches adding lactic acid dissolves minoxidil providing better penetration of minoxidil. Therefore, a skilled artisan would have been motivated to add an acid to form a minoxidil acid salt for enhanced penetration of minoxidil into the hair follicle."

Regarding rejection **B**, the Examiner asserts that it would have been obvious to the skilled artisan "to combine the teachings of the above references and substitute the exemplified propylene glycol with the instantly claimed glycerol and arrive at the instant invention" because "Uchikawa et al. teach both propylene glycol and glycerol are polyhydric alcohols conventionally used in the art."

With regard to both rejections **A** and **B**, in response to Applicants' submission of data to show commercial success, the Examiner asserts the following: (i) that such results are "not convincing because applicant has not compared the alleged successful results to the closest prior art, in this case, Peck" and that "According to MPEP 716.02, an affidavit or declaration under 37 CFR 1.132 must compare the

claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. *In re Burckel*, ... Thus, in order to be persuasive, applicant must demonstrate that the presently claimed invention has had a bigger success commercially than the invention of Peck"; (ii) that "Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. *In re Tiffin*,...As such, since Peck, teaches 10% propylene glycol and the instant claims suggest up to 10% propylene glycol, applicant should be comparing minoxidil compositions within this range of co-solvent in order to be commensurate in scope with the instant claims. However, it is unclear form applicant's description how much propylene glycol is present in MTS and whether or not higher concentrations of propylene glycol in MTF would have as much success"; and (iii) that "Gross sales figures do not show commercial success absent evidence as to market share, ...or as to the time period during which the product was sold, or as to what sales would normally be expected in the market...." (Emphasis in Original)

Applicants note that with regard to (i) and (ii) above, the Examiner appears to be confusing commercial success with unexpected results. More specifically, to show commercial success, successful results are **NOT** compared to the closest prior art. The Examiner points to MPEP 716.02, however this section of the MPEP is directed to unexpected results, i.e., "716.02 Allegations of Unexpected Results - 700 Examination of Applications." Please *see* MPEP 716.02 and 716.03, and the

PowerPoint "37 CFR §1.132 Practice" by Jean Witz, Quality Assurance Specialist, TC 1600.

In view of the arguments with regard to Peck et al., Yu et al., and/or Uchikawa et al., presented in the response filed on December 2, 2009 in the present application, and presented in the supplemental response filed on February 3, 2010 in the present application, each of which response is incorporated herein by reference in its entirety, Applicants submit that a *prima facie* case of obviousness has not been established. In view of the foregoing and the previously presented arguments, it is submitted that nothing in the applied references, taken alone or together, render the presently claimed subject matter obvious within the meaning of 35 USC § 103. Accordingly, the Examiner is respectfully requested to withdraw these rejections of claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-161.

Assuming *arguendo* that a case of *prima facie* obviousness has been established, in view of the secondary considerations discussed below, these rejections are respectfully traversed.

II. SECONDARY CONSIDERATIONS

With regard to each of the above discussed 103 rejections, assuming *arguendo* that a *prima facie* case of obviousness has been established, Applicants submit that the below discussed evidence is sufficient to rebut any case of *prima facie* obviousness.

With regard to rebuttal of a *prima facie* case of obviousness, MPEP §2145

states the following:

> Rebuttal evidence may include evidence of "secondary considerations," such as "commercial success, long felt but unsolved needs, [and] failure of others." *Graham v. John Deere Co.*, 383 U.S. at 17, 148 USPQ at 467. See also, e.g., *In re Piasecki*, 745 F.2d 1468, 1473, 223 USPQ 785, 788 (Fed. Cir. 1984) (commercial success). Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties. *Dillon*, 919 F.2d at 692-93, 16 USPQ2d at 1901. A showing of unexpected results must be based on evidence, not argument or speculation. *In re Mayne*, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997) ... A conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the public in possession of the claimed invention....
>
> Consideration of rebuttal evidence and arguments requires Office personnel to weigh the proffered evidence and arguments. Office personnel should avoid giving evidence no weight, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996). However, to be entitled to substantial weight, the applicant should establish a nexus between the rebuttal evidence and the claimed invention, i.e., objective evidence of nonobviousness must be attributable to the claimed invention. The Federal Circuit has acknowledged that applicant bears the burden of establishing nexus....
>
> When considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. See, e.g., *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. *Id....*
>
> For example, a showing of unexpected results for a single member of a claimed subgenus, or a narrow portion of a claimed range would be sufficient to rebut a *prima facie* case of obviousness if a skilled artisan

"could ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof." *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Evidence of the unobviousness of a broad range can be proven by a narrower range when one skilled in the art could ascertain a trend that would allow him to reasonably extend the probative value thereof.). But see, *Grasselli*, 713 F.2d at 743, 218 USPQ at 778 ... Accordingly, each case should be evaluated individually based on the totality of the circumstances....

Evidence pertaining to secondary considerations must be taken into account whenever present; ...See, e.g., *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372, 82 USPQ2d 1321, 1339 (Fed. Cir. 2007) ... Office personnel should not evaluate rebuttal evidence for its "knockdown" value against the *prima facie* case, *Piasecki,* 745 F.2d at 1473, 223 USPQ at 788, or summarily dismiss it as not compelling or insufficient. If the evidence is deemed insufficient to rebut the *prima facie* case of obviousness, Office personnel should specifically set forth the facts and reasoning that justify this conclusion.

A. Evidence of Commercial Success

"Commercial Success" is discussed in MPEP 716.03(a)-(b), i.e., "716.03 Commercial Success [R-2] - 700 Examination of Applications." MPEP 716.03 recites the following:

I. < NEXUS BETWEEN CLAIMED INVENTION AND EVIDENCE OF COMMERCIAL SUCCESS REQUIRED

An applicant who is asserting commercial success to support its contention of nonobviousness bears the burden of proof of establishing a nexus between the claimed invention and evidence of commercial success.

The Federal Circuit has acknowledged that applicant bears the burden of establishing nexus, stating:

In the *ex parte* process of examining a patent application, however, the PTO lacks the means or resources to gather evidence which supports or refutes the applicant's assertion that the sale constitutes commercial success. *C.f. Ex parte Remark*, 15 USPQ2d 1498, 1503

(Bd. Pat. App. & Int. 1990)(evidentiary routine of shifting burdens in civil proceedings inappropriate in *ex parte* prosecution proceedings because examiner has no available means for adducing evidence). Consequently, the PTO must rely upon the applicant to provide hard evidence of commercial success.

In re Huang, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996). See also *In re GPAC*, 57 F.3d 1573, 1580, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); *In re Paulsen*, 30 F.3d 1475, 1482, 31 USPQ2d 1671, 1676 (Fed. Cir. 1994) (Evidence of commercial success of articles not covered by the claims subject to the 35 U.S.C. 103 rejection was not probative of nonobviousness).

The term "nexus" designates a factually and legally sufficient connection between the evidence of commercial success and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir. 1988).

716.03(a) Commercial Success Commensurate in Scope With Claimed Invention [R-2]

I. < EVIDENCE OF COMMERCIAL SUCCESS MUST BE COMMENSURATE IN SCOPE WITH THE CLAIMS

Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. *In re Tiffin*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971) (evidence showing commercial success of thermoplastic foam "cups" used in vending machines was not commensurate in scope with claims directed to thermoplastic foam "containers" broadly). In order to be commensurate *>in< scope with the claims, the commercial success must be due to claimed features, and not due to unclaimed features. *Joy Technologies Inc. v. Manbeck*, 751 F. Supp. 225, 229, 17 USPQ2d 1257, 1260 (D.D.C. 1990), *aff'd*, 959 F.2d 226, 228, 22 USPQ2d 1153, 1156 (Fed. Cir. 1992) (Features responsible for commercial success were recited only in allowed dependent claims, and therefore the evidence of commercial success was not commensurate in scope with the broad claims at issue.).

An affidavit or declaration attributing commercial success to a product or process "constructed according to the disclosure and claims of [the]

patent application" or other equivalent language does not establish a nexus between the claimed invention and the commercial success because there is no evidence that the product or process which has been sold corresponds to the claimed invention, or that whatever commercial success may have occurred is attributable to the product or process defined by the claims. *Ex parte Standish*, 10 USPQ2d 1454, 1458 (Bd. Pat. App. & Inter. 1988).

II. < REQUIREMENTS WHEN CLAIMED INVENTION IS NOT COEXTENSIVE WITH COMMERCIAL PRODUCT OR PROCESS

If a particular range is claimed, applicant does not need to show commercial success at every point in the range. "Where, as here, the claims are directed to a combination of ranges and procedures not shown by the prior art, and where substantial commercial success is achieved at an apparently typical point within those ranges, and the affidavits definitely indicate that operation throughout the claimed ranges approximates that at the particular points involved in the commercial operation, we think the evidence as to commercial success is persuasive." *In re Hollingsworth*, 253 F.2d 238, 240, 117 USPQ 182, 184 (CCPA 1958). *See also Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir. 1988) (where the commercially successful product or process is not coextensive with the claimed invention, applicant must show a legally sufficient relationship between the claimed feature and the commercial product or process).

Case law regarding commercial success is discussed below.

A high volume of products sold coupled with evidence of increasing market share has been found persuasive evidence of commercial success. *See Ashland Oil Inc. v. Delta Resins & Refractories Inc.*, 776 F.2d at 291 (Fed. Cir. 1985). Once commercial success of a product embodying the claimed subject matter has been established, Applicants must still demonstrate a nexus between the commercial success of the product and the claimed features, i.e., the claimed features are

responsible for the product's commercial success. *See Ashland Oil*, 776 F. 2d at 305-306. Such "nexus" can be shown, for example, by an affidavit from the purchaser explaining that the product was purchased due to the claimed features. *See In re Ben Huang*, 100 F.3d 135 (Fed. Cir. 1996). When a patent owner demonstrates that there are significant sales in a relevant market and the successful product is disclosed and claimed in the patent, a presumption arises that there is a nexus. *See Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006). Thereafter, the burden shifts to the party asserting obviousness to present evidence to rebut the presumed nexus by establishing that the commercial success is due to other factors. *See J. T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co.*, 106. F.3d 1563, 1571(Fed. Cir. 1997).

Submitted herewith is a Declaration under 37 CFR §1.132 by John Richard Buchta (the "Buchta Declaration"), Director of Stiefel Research Australia Pty. Ltd., which is the assignee of the present application. The Declaration demonstrates the commercial success of the presently claimed pharmaceutical composition and methods of using the same.

The Buchta Declaration demonstrates the following:

1. That the product sold, i.e., Rogaine® foam, is a commercial embodiment of the subject matter recited in amended claim 1 and present claim 21. That is, Appendix A evidences that the product, i.e., Rogaine® foam, which has been sold, corresponds to the presently claimed subject matter. *See* Appendix A which is a copy of the packaging from Rogaine® foam, and the Buchta Declaration, at paragraphs 2 and 6.

2. That Rogaine® foam was first approved for sale in the United States in January 2006. *See* paragraph 7 of the Buchta Declaration.

3. That the relevant market is topical treatments for consumers suffering from thinning hair/baldness/hair loss in the United States. *See* paragraph 8 of the Buchta Declaration.

4. Since its launch in 2006, Rogaine® foam's market share (based on dollar volume/unit volume) in the United States has increased nearly six times (from 5%/3% in 2006 to 28%/17% in 2010) in less than four years. This increase in market share is a clear indicator of the commercial success of Rogaine® foam, resulting from the claimed features discussed above. In addition, for each year, the fact that the market share based on dollar volume data is significantly greater than market share based on unit volume data establishes that Rogaine® foam is being sold at a price premium.

   See paragraphs 3 and 9 of the Buchta Declaration, and Appendix B which is a Table spread across three pages, showing the Market Share of Rogaine® foam sold in the United States, based on both dollar volume and unit volume. The data for Rogaine® foam is illustrated in the first eight (8) rows of Appendix B, and the remaining rows correspond to other topical treatments for consumers suffering from thinning hair/baldness/hair loss on the market in the United States from 2006 thru March 2010.

5. That the sampling of positive consumer responses shown in Appendix C and Appendix D evidences the nexus between the commercial success and the subject matter claimed in amended independent claim 1 and independent claim 21. More specifically, the positive consumer responses shown establish that the sales of Rogaine® foam were a direct result of the unique characteristics of the subject matter of amended independent claim 1 and independent claim 21 and not due to other factors. *See* paragraphs 4, 5 and 10 of the Buchta Declaration, Appendix C and Appendix D.

In view of the foregoing, the Buchta Declaration, and Appendices A-D, it is submitted that the commercial success of Rogaine® foam has been clearly demonstrated. Accordingly, Applicants assert that any alleged case of *prima facie* obviousness has been rebutted. Thus, the Examiner is respectfully requested to

withdraw the 103 rejections of claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-161.

Regarding the Examiner's assertions (i)–(iii) discussed above, Applicants submit the following:

Regarding assertion (i), that such results are "not convincing because applicant has not compared the alleged successful results to the closest prior art, in this case, Peck" and that "According to MPEP 716.02, an affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. *In re Burckel*,... Thus, in order to be persuasive, applicant must demonstrate that the presently claimed invention has had a bigger success commercially than the invention of Peck," the Examiner appears to be confusing commercial success with unexpected results. More specifically, to show commercial success, successful results are **NOT** required to be compared to the closest prior art, i.e., "Peck." The Examiner points to MPEP 716.02, however this section of the MPEP is directed to unexpected results, i.e., "716.02 Allegations of Unexpected Results - 700 Examination of Applications," rather than to evidence of commercial success. Please *see* the PowerPoint "37 CFR §1.132 Practice" by Jean Witz, Quality Assurance Specialist, TC 1600, and MPEP 716.03.

With regard to assertion (ii), that "Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. *In*

re Tiffin,...As such, since Peck, teaches 10% propylene glycol and the instant claims suggest up to 10% propylene glycol, applicant should be comparing minoxidil compositions within this range of co-solvent in order to be commensurate in scope with the instant claims. However, it is unclear from applicant's description how much propylene glycol is present in MTS and whether or not higher concentrations of propylene glycol in MTF would have as much success," Applicants submit that the present claims recite, in part, "propylene glycol is present in an amount of less than 10% by weight...." That is, the present claims encompass a product, i.e., Rogaine® foam, containing 0% propylene glycol. Thus, as discussed above, the commercial product, i.e. Rogaine® foam, falls within the present claims. Further, Applicants note that if a particular range is claimed, Applicant does not need to show commercial success at every point in the range. *See In re Hollingsworth*, 253 F.2d 238, 240, 117 USPQ 182, 184 (CCPA 1958).

As to assertion (iii), that "Gross sales figures do not show commercial success absent evidence as to market share, ...or as to the time period during which the product was sold, or as to what sales would normally be expected in the market...," (Emphasis in Original) Applicants have provided evidence as to market share despite the Examiner's indication to the contrary. Please *see* the above discussions as to market share, the Buchta Declaration at paragraphs 3 and 9, and Appendix B.

In view of the foregoing, Applicants submit that the Buchta Declaration

demonstrates that there are significant sales in a relevant market and the successful product, i.e., Rogaine® foam, is disclosed and claimed in the present application; thus, there is a presumption that there is a nexus. *See Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006), the Buchta Declaration and Appendix B. Further, the Buchta Declaration establishes such a "nexus" by showing that the claimed features are responsible for Rogaine® foam's commercial success. *See* the Buchta Declaration and Appendices C and D. Thus, Applicants submit that the Buchta Declaration and Appendices A-D clearly establish the commercial success of Rogaine® foam and that the claimed features are responsible for Rogaine® foam's commercial success. Accordingly, Applicants assert that any alleged case of *prima facie* obviousness has been rebutted. Thus, the Examiner is respectfully requested to withdraw the 103 rejections of claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-161.

Assuming arguendo that the Examiner is of the opinion that a "nexus" has not been established, Applicants assert that the Buchta Declaration and Appendices A-D, clearly establish significant sales in a relevant market and the successful product, i.e., Rogaine® foam, is disclosed and claimed in the present application. Thus, there is a presumption that there is a nexus. Accordingly, the Examiner is reminded that the burden shifts to the party asserting obviousness, i.e., the USPTO, to present evidence to rebut the presumed nexus by establishing that the

commercial success is due to other factors. *See J. T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co.*, 106. F.3d 1563, 1571(Fed. Cir. 1997).

In view of the foregoing, Applicants again submit that any *prima facie* case of obviousness is rebutted by the Buchta Declaration submitted herewith illustrating the commercial success of the claimed minoxidil compositions and methods. Accordingly, the Examiner is respectfully requested to withdraw the 103 rejections of claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-161.

CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP

Joshua B. Goldberg
Registration No. 44,126
Susanne M. Hopkins
Registration No. 33,247
Customer No. 90434

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THE NATH LAW GROUP
112 South West Street
Alexandria, Virginia 22314
Tel: (703) 548-6284
Fax: (703) 683-8396